

Abstract

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RETROSPECTIVE ALGORITHM AND EARLY CLINICAL OUTCOMES IN EMERGENCY HAEMOSTATIC SURGERY FOR PATIENTS WITH UPPER GASTROINTESTINAL BLEEDING

Background. None of the therapeutic methods guarantee ideal haemostasis for a patient with gastrointestinal bleeding. An open surgical intervention is always recommended in certain difficult cases. This work presents a single-center retrospective study of clinical outcomes for surgical haemostasis in patients with upper gastrointestinal bleeding of a different nature, also with a development of the semi-formal nature's retrospective algorithm (graph-scheme with word content).

Patients and Methods. Sixty one patients were operated urgently for uncontrolled nontraumatic upper gastrointestinal bleedings in Sumy Regional Clinical Hospital between 2009/01 and 2014/02. In a final analysis included 58 persons: a «General» group (n = 58; all upper gastrointestinal bleedings), an «Ulcer bleedings» group (n = 35; gastroduodenal bleedings from ulcers or erosions, operated stomach's ulcers-erosions) and a «Nonulcer bleedings» group (n = 23; gastric cancer, Mallory –Weiss syndrome, cirrhotic varice, perforated ulcer, bleeding with obstruction).

Results. The clinical effectiveness in the surgical haemostasis was in 45 (78 %) persons of the «general» group, among the «Ulcer bleedings» group in 28 (80 %) persons and the «Nonulcer bleedings» group in 17 (74 %) persons. The postoperative mortality according to the three groups occurred in 22 %, 20 % and 26 %, respectively. The indications for reoperation (9 % of total) were bleeding recurrences (3 patients) and peritonitis (2 patients).

Conclusions: The algorithm gives a simplified scheme of clinical perception of early results on the operative approach by ligature or resection haemostasis. This will serve for educational and analytical tool to a new single- or multicenter studies design of high evidence.

Keywords: gastrointestinal bleeding, surgery, outcomes, algorithm.

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Резюме

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РЕТРОСПЕКТИВНИЙ АЛГОРИТМ ТА РАННІ КЛІНІЧНІ НАСЛІДКИ НЕВІДКЛАДНОЇ ГЕМОСТАТИЧНОЇ ХІРУРГІЇ ДЛЯ ХВОРИХ НА ВЕРХНЮ ШЛУНКОВО-КИШКОВУ КРОВОТЕЧУ

Вступ. Жоден з лікувальних методів не гарантує ідеального гемостазу для хворого на шлунково-кишкову кровотечу. Оперативне втручання завжди вимушений шлях для деяких тяжких випадків. Дана робота презентує одноцентрове ретроспективне дослідження клінічних наслідків хірургічного гемостазу для хворих на верхню шлунково-кишкову кровотечу різ-

ної природи, також розроблено півформальний ретроспективний алгоритм (граф-схема зі словесним змістом).

Пацієнти і методи. Ми спостерігали шістдесят одного хворого, прооперованого невідкладно з приводу неконтрольованої нетравматичної верхньої шлунково-кишкової кровотечі у Сумській обласній клінічній лікарні з 2009/01 по 2014/02. У заключний аналіз включено 58 осіб: «загальна» група (n = 58; усі верхні шлунково-кишкові кровотечі), «виразкова» група (n = 35; гастродуоденальні кровотечі з виразок і ерозій, в т.ч. оперованого шлунка) і «невиразкова» група (n = 23; рак шлунка, синдром Мелорі–Вейса, циротичний варикоз, перфоративна виразка, кровотеча зі стенозом).

Результати. Клінічна ефективність хірургічного гемостазу була у 45 (78 %) осіб «загальної» групи, 28 (80 %) осіб з «Виразкової» групи та 17 (74 %) осіб з «невиразкової» групи. Післяопераційна летальність згідно груп була 22 %, 20 % та 26 %, відповідно. Показаннями до реоперації (n = 5; 9 % від усіх оперованих) стали рецидиви кровотечі (3 хворих) і перитоніт (2 хворих).

Висновки. Застосований алгоритм дає спрощену схему клінічного сприйняття ранніх результатів оперативного лікування з прошивання та резекціями. Він слугуватиме аналітично-освітнім засобом для дизайну нових одно- та багатоцентрових високодоказових досліджень.

Ключові слова: шлунково-кишкова кровотеча, хірургія, наслідки, алгоритм.

Резюме

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РЕТРОСПЕКТИВНЫЙ АЛГОРИТМ И РАННИЕ КЛИНИЧЕСКИЕ РЕЗУЛЬТАТЫ НЕОТЛОЖНОЙ ГЕМОСТАТИЧЕСКОЙ ХИРУРГИИ ДЛЯ БОЛЬНЫХ С ВЕРХНИМ ЖЕЛУДОЧНО-КИШЕЧНЫМ КРОВОТЕЧЕНИЕМ

Вступление. Ни один из лечебных методов не гарантирует идеальный гемостаз для больного с желудочно-кишечным кровотечением. Оперативное вмешательство всегда вынужденный путь в некоторых тяжелых случаях. Данная работа представляет одноцентровое ретроспективное исследование клинических результатов хирургического гемостаза для больных с верхним желудочно-кишечным кровотечением разной природы, также разработан полупформальный ретроспективный алгоритм (граф-схема со словесным содержанием).

Пациенты и методы. Шестьдесят один больной был прооперирован неотложно в связи с неконтролируемым нетравматическим верхним желудочно-кишечным кровотечением в Сумской областной клинической больнице с 2009/01 по 2014/02. Для заключительного анализа включено 58 больных: «общая» группа (n = 58; все верхние желудочно-кишечные кровотечения), «язвенная» группа (n = 35; гастродуоденальные кровотечения из язв и эрозий, в т.ч. оперированного желудка) и «неязвенная» группа (n = 23; рак желудка, синдром Мелори–Вейса, циротический варикоз, перфоративная язва, кровотечение со стенозом).

Результаты. Клиническая эффективность хирургического гемостаза была у 45 (78 %) больных «общей» группы, 28 (80 %) боль-

ных из «язвенной» группы и 17 (74 %) больных из «неязвенной» группы. Послеоперационная летальность согласно группам была 22 %, 20 % и 26 %, соответственно. Показаниями для реоперации (n = 5; 9 % всех оперированных) стали рецидивы кровотечения (3 больных) и перитонит (2 больных).

Выводы. Использованный алгоритм дает упрощенную схему клинического восприятия ранних результатов оперативного лечения с прошиванием и резекциями. Он будет служить аналитико-образовательным средством для дизайна новых одно- и многоцентровых высокодоказательных исследований.

Ключевые слова: желудочно-кишечное кровотечение, хирургия, результаты, алгоритм.

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Вступ

Today clinical effective possibilities exist in endoscopic and pharmacological methods of haemostasis correction for upper gastrointestinal bleedings of any nature. However a classical open surgery continues to be a «gold standard» also, leaving no alternative in most severe patients.

Recently in the hospitals with a sophisticated infrastructure some minds are appearing about a death of the open surgery for ulcer disease because the endovascular approach excludes it supposedly [1]. Nevertheless, this reasoning is not related to a reality, where a classical open surgery is used widely even if the minimally invasive interventional procedures are becoming the method of choice. Up to the literature data on patients with the ulcer disease, the quantity of emergency surgical interventions for bleeding ulcers has increased to 44 % against programmed interventions [2]. Parallel to this, it is constated the 10-fold decrease of the surgical activity for the programmed sanation in patients with the ulcer disease [3].

Topicality of the problem. A choice of the best «aggressive» method and of the optimal volume for bleeding control depends mostly on the surgical team's experience and the hospital's resources, where the patient treats [4–5]. In this context, a few medical centers have made attempts to implement a unified surgical approach (protocol) which gave a successful decrease in mortality rate from 14 % to 5 % [6–7]. However, a real employment in a practice of the unified surgical approach is still difficult because of a large variety of the upper gastrointestinal bleeding's nature (ulcer, cancer, varice, etc.) among patients. This fact complicates a unified surgical decision-making [8,9]. With regards on the above-said, a study of retrospective experience would present the whole image of «routine» emer-

gency situations with patients with upper gastrointestinal bleeding; consequently, this will give observational evidence to develop a future unified algorithm.

The aim of the study is to present clinical outcomes for open surgical haemostasis in patients with upper gastrointestinal bleeding, and for the first time to develop a retrospective algorithm of operation decision-making.

Materials and Methods

Data collection

A total of 61 operated patients were analyzed in the study. The data collection was between 1 January 2009 and 10 February 2014 (the date of hospitalization of the last included patient). The collection of documented information was realized on the local electronic database of in-patients of Sumy Regional Clinical Hospital and the official operation and admission journals for in-patients (Scheme 1).

The inclusion criteria for selection of patients were the following: persons with age > 18 years old; persons operated in emergency order during the study period and in the Surgical Unit of Sumy Regional Clinical Hospital; persons operated for a nontraumatic gastrointestinal bleeding with bleeding's localization in the upper gastrointestinal tract (stomach, duodenum), classified with Forrest 1 type and/or bleeding's stigmata in the gastroduodenal lumen. After the selection the retrospective algorithm included also 2 patients with low gastrointestinal bleedings of the tumor nature and 1 patient with a fulminant pancreonecrosis, complicated by intra-abdominal bleeding. Finally the outcome analysis did not include the latter 3 patients. All the patients (58 from 61 selected) divided into three groups according to the disease category: 58 persons reunited in a «General» group (all upper gas-

trointestinal bleedings), 35 persons from the «General» group presented a «Ulcer bleedings» group (ulcers, erosions, ulcers-erosions of operated stomach), 23 persons from the «General» group presented a «Nonulcer bleedings» group (stomach cancer, Mallory–Weiss syndrome, isolated varices of cirrhotic nature, varices of cirrhotic nature combined with ulcers or erosions, perforated bleeding ulcer, bleeding ulcer with stomach stenosis).

The outcome analysis considered separately patients with a ligature surgery and patients with a radical surgery. The ligature surgery included the following: oversewing of bleeding zones, ulcerectomies (atypical edge excision, so-called «economic» ulcerectomy, or complete circular excision, respectively «radical» ulcerectomy) with or without pyloroduodenoplasty. The radical surgery was defined as all other operations with partial or total gastric resections.

Nature of the bleedings and structure of the groups

In the «General» group the men were 6-fold more than the women: 50 men, 8 women. In the «Ulcer bleedings» group the men were 4-fold more than the women: 28 and 7, respectively. In the «Nonulcer bleedings» group the men were 22-fold more than the women: 22 and 1. The average age in the «General» group was 52 ± 12 years: among the women from 32 to 64 years old, among the men from 21 to 74 years old. In the «Ulcer bleedings» group the average age was 50 ± 12 years (range 21–74 years), in the «Nonulcer bleedings» group it was 55 ± 13 years (range 26–72 years).

Fifty four (93 %) patients had a fibroesophagogastrroduodenoscopy before the surgery. Two (6 %) of the «Ulcer bleedings» group and 2 (7 %) of the «Nonulcer bleedings» group had a fibroesophagogastrroduodenoscopy «on operating table» after premedication preparation.

Among the persons of the «Ulcer bleedings» group ($n = 35$) there were 29 (83 %) patients with chronic ulcer disease (24 patients with duodenal ulcer disease, 4 patients with gastric ulcer disease, 1 patient with gastro-duodenal ulcer disease); also, the «Ulcer bleedings» group included 4 (11 %) patients with erosions (1 patient with acute erosive gastritis, 1 patient with chronic erosive duodenitis, 1 patient with chronic gastro-duodenal ulcer and erosive disease, 1 patient with chronic ulcer and erosive disease of the operated stomach after Bill-

roth type 2) and 2 (6 %) patients with acute gastric ulcer disease. The «Nonulcer bleedings» group ($n = 23$) included 8 (35 %) patients with gastric cancer, 7 (30 %) patients with varicose bleeding from the cardia caused by the hepatic cirrhosis (3 from 7 patients with combined varicose lesions: 1 patient with varicose bleeding and chronic gastric ulcer disease, 1 patient with varicose bleeding and chronic ulcer disease of operated stomach after Billroth type 2, 1 patient with varicose bleeding and acute gastric erosive disease); 4 (17 %) patients with Mallory–Weiss syndrome, 2 (9 %) patients with perforative duodenal bleeding ulcer and 2 (9 %) patients with subcompensated pylorostenosis and chronic duodenal ulcer disease.

Statistical analysis

The elementary methods of statistics used: percentage and mean calculations, standard deviations with a help of Internet-based Math Calculator and Converter [10] and Microsoft Office Excel (2007, USA). The algorithm's visualization was made on Microsoft Office Word (2007, USA).

The comparisons of primary (post-operative mortality rates) and secondary (reoperation rate) outcomes were done with the Fisher's exact test, two-sided with $p < 0.05$ as a significance threshold. The statistical analysis did not consider the inflation risk of p-threshold for the primary outcomes. The comparison analysis employed Internet-based statistical freeware BiostaTGV (Pierre Louis Institute of Epidemiology and Public Health, Paris, France) [11].

Ethics of the study

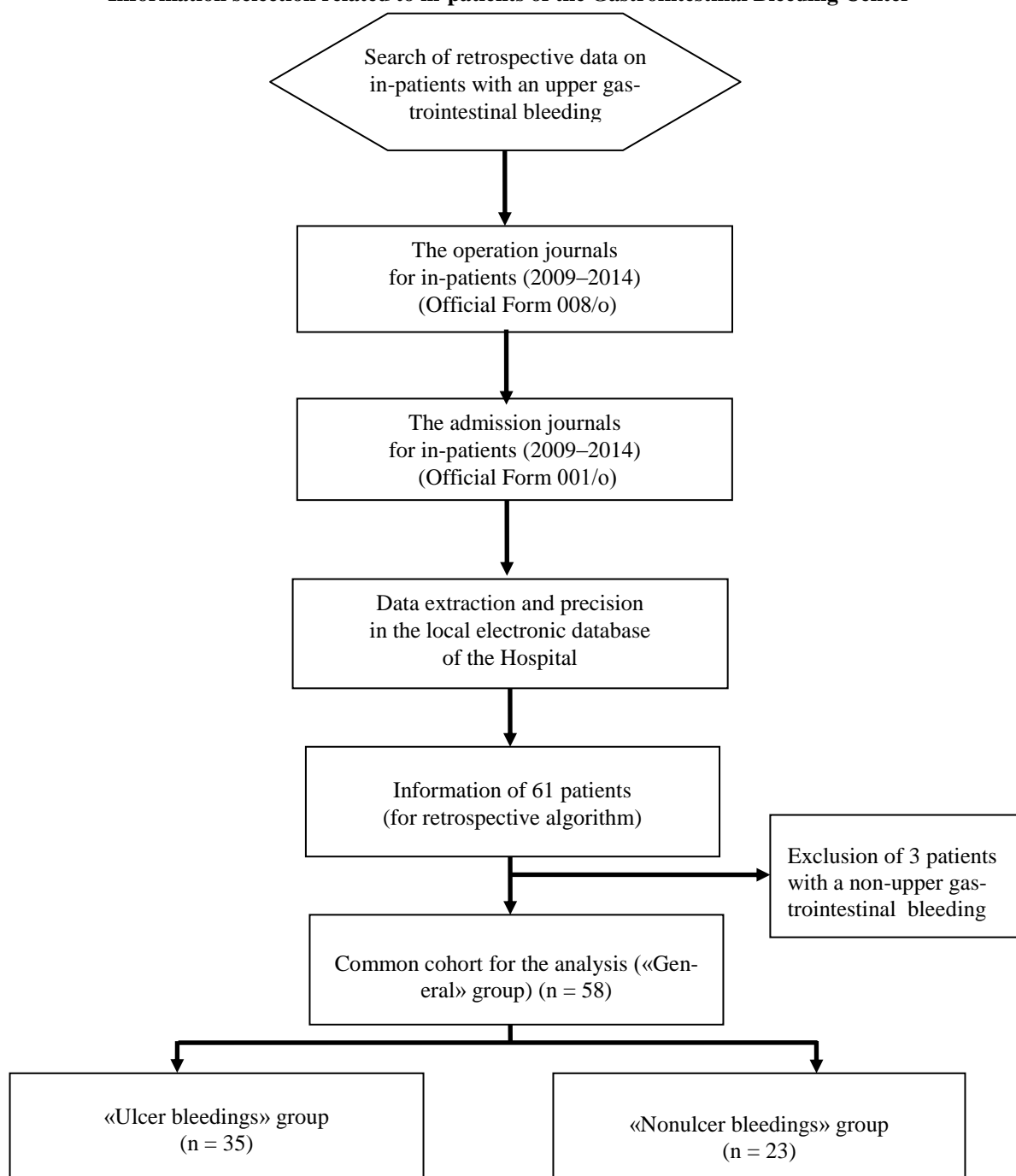
The data were collected and analyzed using the local institutional rules of ethics for Sumy Regional Clinical Hospital and Sumy State University (Sumy, Ukraine) with anonymity masking. The scientific work was treated and approved by the Commission on Bioethics of the Medical Institute of Sumy State University on 07.04.2015 (Protocol # 1/4).

After the medical and surgical treatment the majority of patients in all the groups were discharged in a good clinical condition for ambulatory follow-up: 45 (78 %) patients in the «General» group, 28 (80 %) patients in the «Ulcer bleedings» group, 17 (74 %) patients in the «Nonulcer bleedings» group. The surgical decision-making and their outcomes are presented in Algorithm 1 and Table 1.



Scheme 1

Information selection related to in-patients of the Gastrointestinal Bleeding Center



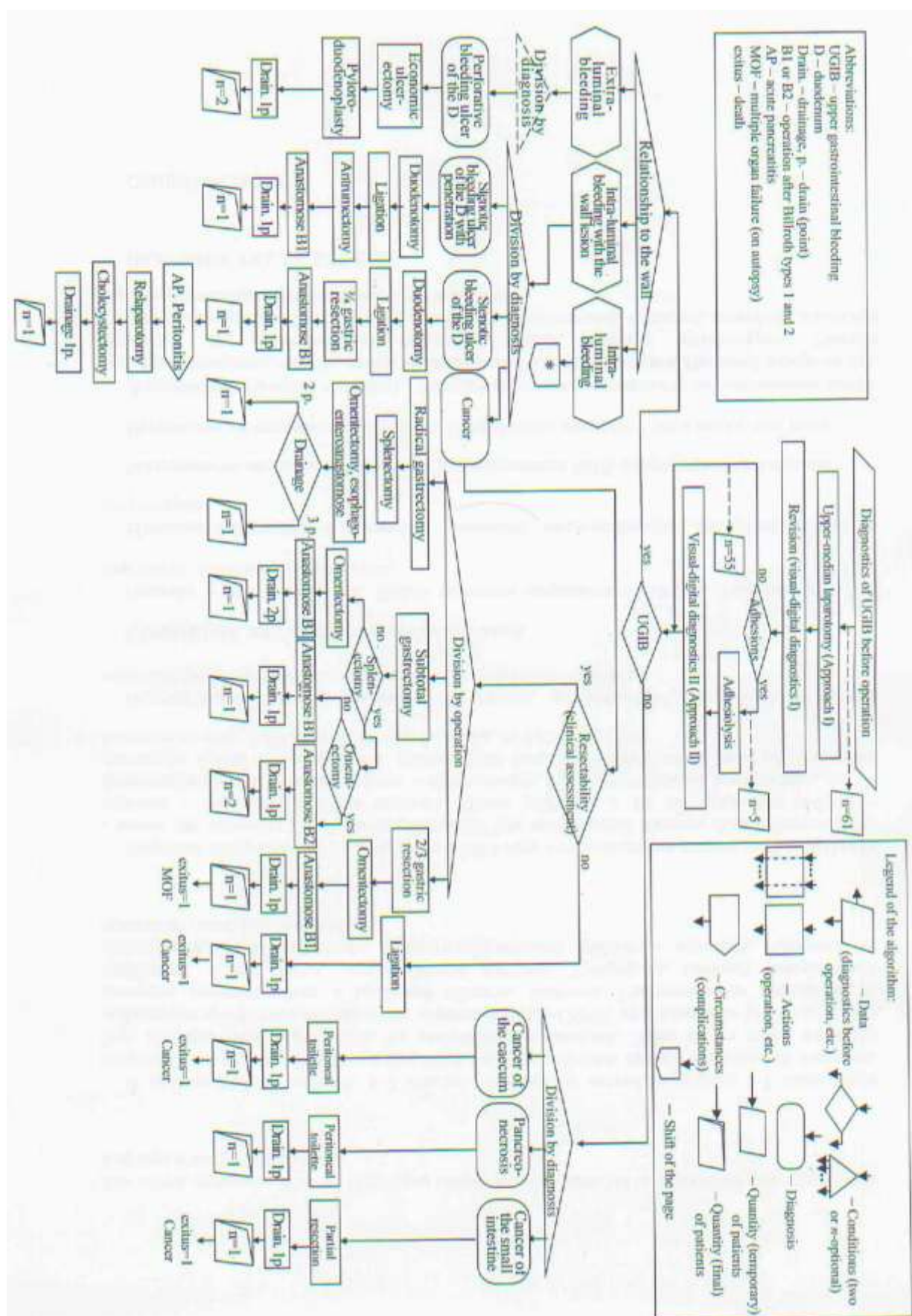
Results

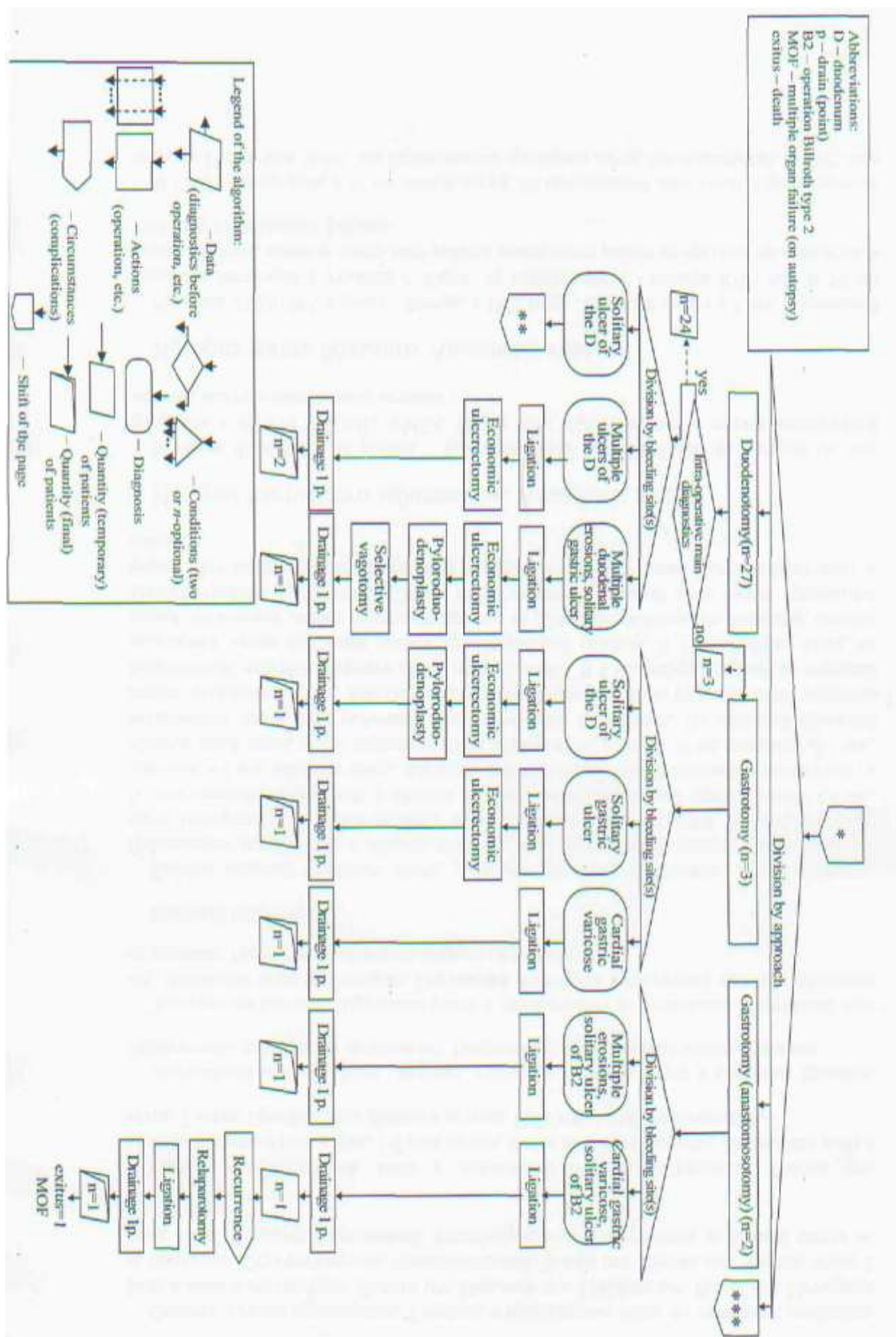
The death from a multiple organ failure occurred in 7 (54 %) patients of the «General» group, the death from an acute hepatic failure was in 3 (23 %) patients, 1 (8 %) patient died from a cancer intoxication, 1 (8 %) patient died from a chronic

lympholeucosis, 1 (8 %) patient died from a pulmonary embolism. In 2 (3 %) patients the autopsy was not performed because of refusal by the patient's kin. No pathological disagreement with the clinical diagnosis was detected.

Algorithm 1

Tree of clinical situations and algorithm of accepted surgical decision-making





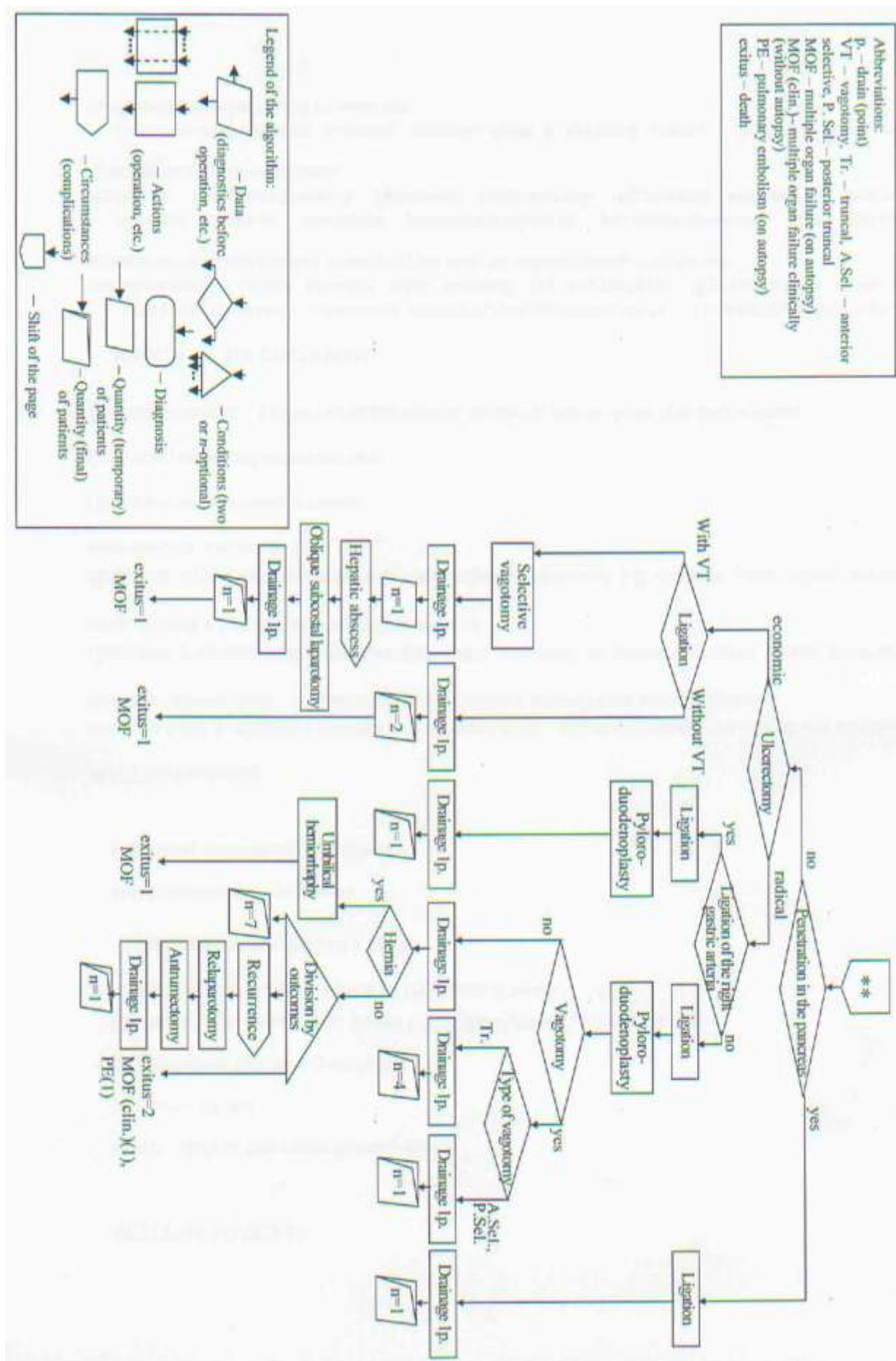




Table 1 Clinical results for operated in-patients with upper gastrointestinal bleeding

Outcome	Groups			p ^F
	«General» (n = 58)	«Ulcer bleedings» (n = 35)	«Nonulcer bleedings» (n = 23)	
Primary clinical outcomes (mortality)				>0.5
Overall (hospital) post-operative mortality, n (%)	13 of 58 (22 %)	7 of 35 (20 %)	6 of 23 (26 %)	
Post-operative mortality after the ligature surgery, n (%)	12 of 45 (27 %)	7 of 32 (22 %)	5 of 13 (38 %)	
Post-operative mortality after the radical surgery, n (%)	1 of 13 (8 %)	0 of 3 (0 %)	1 of 10 (10 %)	
Mortality during the first post-operative day, n (%)	5 of 58 (9 %)	2 of 35 (6 %)	3 of 23 (13 %)	
Mortality, if the operation performed in the first 24 hours after admission, n (%)	4 of 19 (21 %)	1 of 9 (11 %)	3 of 10 (30 %)	
Mortality, if the operation performed after the first 24 hours after admission, n (%)	9 of 39 (23 %)	6 of 26 (23 %)	3 of 13 (23 %)	
Mortality after reoperation for the bleeding recurrence, n (%)	1 of 2 (50 %)	0 of 0 (0 %)	1 of 2 (50 %)	
Mortality after reoperation for the surgical non bleeding complications, n (%)	1 of 1 (100 %)	1 of 1 (100 %)	0 of 0 (0 %)	
Secondary clinical outcomes (reoperation – second laparotomy)				
Reoperations, n (%)	5 of 58 (9 %)	2 of 35 (6 %)	3 of 23 (13 %)	
Reoperations after the radical surgery, n (%)	1 of 13 (8 %)	0 of 3 (0 %)	1 of 10 (10 %)	
Reoperations after the ligature surgery, n (%)	4 of 45 (9 %)	2 of 32 (6 %)	2 of 13 (15 %)	
Reoperations after the bleeding recurrence, n (%)	3 of 58 (5 %)	1 of 35 (3 %)	2 of 23 (9 %)	
Reoperations after the surgical non bleeding complications, n (%)	2 of 58 (3 %)	1 of 35 (3 %)	1 of 23 (4 %)	
F calculation with the Fisher's exact test				

The average duration of the first emergency haemostatic operation in the «General» group lasted 110 ± 46 minutes, in the «Ulcer bleedings» group it was 94 ± 31 minutes, in the «Nonulcer bleedings» group it was 132 ± 54 minutes. The average duration of the emergency operation performed in the first 24 hours after admission was 108 ± 46 minutes, 90 ± 29 minutes and 122 ± 52 minutes in the «General» group, in the «Ulcer bleedings» group and in the «Nonulcer bleedings», respectively. The average duration of the emergency operation performed after the first 24 hours after admission 104 ± 39 minutes, 95 ± 33 minutes and 125 ± 46 minutes in the «General» group, in the «Ulcer bleedings» group and in the «Nonulcer bleedings», respectively. In

the «General» group, the average duration was 168 ± 39 minutes for the first radical haemostatic operation and 91 ± 31 minutes for the first ligature haemostatic operation. In the «Ulcer bleedings» group, the average duration was 135 ± 30 minutes for the first radical haemostatic operation and 89 ± 29 minutes for the first ligature haemostatic operation. In the «Nonulcer bleedings» group, the average duration was 179 ± 37 minutes for the first radical haemostatic operation and 97 ± 35 minutes for the first ligature haemostatic operation.

In total, the average duration of in-patient hospital stay was 17 ± 9 days, 16 ± 8 days and 18 ± 9 days in the «General» group, in the «Ulcer

bleedings» group and in the «Nonulcer bleedings», respectively.

Discussion

Post-operative hospital mortality for patients with upper gastrointestinal bleeding

The open surgical haemostasis was effective in 45 (78 %) patients. A multiple organ failure was the cause of death in more than half of patients (54 %). The ligature surgery was associated with 22 % and 38 % of mortality in the «Ulcer bleedings» group and «Nonulcer bleedings», respectively, while the radical surgery gave 0 % and 10 % of mortality in the «Ulcer bleedings» group and «Nonulcer bleedings» respectively. However, the comparison was not statistically different ($p = 0.7$). If the first operation performed during the first 24 hours after admission the mortality was 11 % and 30 % in the «Ulcer bleedings» group and «Nonulcer bleedings», respectively, while the first operation performed after 24 hours after admission the mortality in the both group was equal (23 %).

The clinical effectiveness can vary between 65,9 and 90 % of operated patients in modern settings [3, 12]. Among the causes of mortality the first place (up to 36 % of deaths) belongs to «non surgical» causes, in particular multiple organ failure [13, 14].

During the surgical haemostasis the technical side is always a very responsible concern. Constantly the individual questions arise in the patient and in the surgeon: should be limited to the ligature surgery or to perform a resection? If yes for resection, what volume is better? The answers on these questions from the evidence-based medicine remain controversial. The relationship between the operation volume and the decrease in the mortality of the operated proved by Czymek R. et al. on their surgical experience of middle-size sample ($n = 91$, including patients with upper gastrointestinal bleeding of different nature) [12]. According to these authors, a significant factor of post-operative mortality risk was a type of resection, especially Billroth types 1 and 2 or edge resection [12].

On the one hand, some surgical schools prefer exclusively the radical surgery as a first operation for the haemostasis, for example, the Russian colleagues estimated the mortality between 0,7 % and 6,6 % if the radical surgery used first [16, 17].

Conversely, a lot of studies did not reveal a significant difference for a surgical haemostasis with different volumes. Millat B. et al. in a prospective randomized multiple-center study ($n = 120$) detected that the mortality was not

different between oversewing with vagotomy versus resections among operated patients with bleeding ulcer [18]. The British surgical team conducted a retrospective analysis of 67 patients with bleeding ulcer: 31 patients with the ligature surgery versus 36 patients with the radical surgery, resulting in an insignificant difference: 16 % versus 19 %, respectively $p > 0.05$ [19]. Cheynel, N., et al., operating 49 patients with bleeding ulcer estimated that the post-operative mortality in different haemostatic surgeries was 20,4 % (10 of 49 patients) without a significant difference [20].

Schroder V.T. et al. have studied 775 operated patients with bleeding ulcer and have concluded that neither the ligature surgery, nor the radical surgery with vagotomy improved the results – (30-days mortality, duration of hospital stay) in comparison with the drainage (plastic) surgery supplemented with vagotomy [15].

Some authors underline that the post-operative mortality decreases, if the operation is delayed. The mortality after the emergency surgery fluctuates between 10 % and 50 %, in case of the urgent surgery it is 4,2 % and the early elective surgery between 0,8 % and 8,1 % [21–23]. Despite these literature data, a definition of the delay for surgery is still doubtful and even undetermined in terms of bleeding and death risk control for clinicians, notably when the active bleeding is diagnosed.

Nowadays the most recommended operations for duodenal ulcers remain excision of the ulcer (ulcerectomy) or antrumectomy with pyloroduodenoplasty after Finsterer, while for gastric ulcers it should be recommended subtotal gastrectomy, radical gastrectomy or ulcerectomy [24–26]. A performance of vagotomy depends on plenty of factors like the surgeon's qualification, the patient's general state, a bleeding recurrence potential, a bleeding localization and its characteristics like a presence of perforation, and others [27–30]. Aga H. et al. supposed that the success in haemostasis depends on a variety of these clinical risks that remain precisely undefined [31].

Early complications after the surgery of upper gastrointestinal bleeding

The indication for reoperation (9 % of total) was bleeding recurrences: 3 (5 %) patients in the «General» group, 1 (3 %) patient in the «Ulcer bleedings» group, 2 (9 %) patients in the «Nonulcer bleedings» group. Early non bleeding surgical complications (3 % in the «General» group) occurred in the both groups, 1 patients of the «Nonulcer bleedings» group had a peritonitis with



acute post-operative pancreatitis and 1 patient of the «Ulcer bleedings» group had a hepatic abscess.

The diagnostics of recurrence of the «old» bleeding site or a development of the new one on the intact mucosa is a clinical challenging task. The most complex search is a detection, especially without angiography, of vascular pathological component of the bleeding (arterial, venous or mixed) in a patient before and after the open operation. The modern non perfect diagnostics of the «bleeder» may result to a situation when the

Висновки

Our algorithm gives a simplified visualization scheme of achieved early surgical results in a single specialized medical center. The presented algorithmization may serve as an analytical instrument for future development of a multi-or single-center clinical trial.

In conclusion, we present firstly a retrospective decision-making tree which makes example of a

Перспективи подальших досліджень

In the future it would be necessary to compare short- and long-term survival with different surgical

Подяка від авторів

The authors had a presentation for an abstract work with 9 operated patients from this study at the 46th World Congress of Surgery, 23–27 August, 2015, Bangkok, Thailand. Kharchenko S.V. ob-

most frequent complication after the first surgery is a bleeding recurrence. In general, the post-operative complications are possible in 14–21 % of operated patients [6, 9, 14, 32]. Meanwhile, a complex of the absolute clinical and the surrogate paraclinical indications is still uncertain for use of an emergency relaparotomy. Some colleagues recommend application of early relaparotomy if it exists a clinical grounded suspicion of a stump insufficiency, a peritonitis, a bleeding recurrence or an abscess of the peritoneal cavity [17].

generalized treatment experience for patients with upper gastrointestinal bleeding. Observed clinical effectiveness for the principal outcome (overall post-operative mortality) after the open surgery was 78 % (45 of 58 patients) for the «General» group, 80 % (28 of 35 patients) for the «Ulcer bleedings» group, 74 % (17 of 23 patients) for the «Nonulcer bleedings» group. This may confirm a situational correctness of the realized algorithm.

volumes which apply to the treatment of patients with upper gastrointestinal bleeding.

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